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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,150

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Takeshi Kawazoe

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WENDEROTH, LIND & PONACK, L.L.P.

1030 15th Street, N.W.,

Suite 400 East

Washington, DC 20005-1503

EXAMINER

JAVANMARD, SAHAR

ART UNIT

PAPER NUMBER

1617

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,150	Applicant(s) KAWAZOE ET AL.	
	Examiner SAHAR JAVANMARD	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/15/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 10/09/2007. Claim(s) 3 and 5-7 are pending. Claim(s) 3 and 5 have been amended. Claim(s) 6 and 7 have been added. Claim(s) 3 and 5-7 are examined herein.

Response to Arguments

Applicant's arguments with respect to the 102(b) rejection of claims 3-5 as being unpatentable over Cappelli-Schellpfeffer (WO 01/70210 A2) have been fully considered but found not persuasive. Cappelli-Schellpfeffer specifically teaches the topical application of aspirin on the surface of a scar or healed wound including keloids (page 3, lines 19-24).

Applicant contends that the reference teaches a healed wound or scar, whereas Applicant is claiming a method of inhibition when the keloid or scar has not yet formed. It is not clear from Applicant's statement of "in a course of therapy of wound or dermal injury," what stage of dermal or wound injury is being referred to. It is not clear if it is at the open wound stage or near the end at the scarring stage. Thus Examiner is interpreting the claims as taught by Cappelli-Schellpfeffer wherein the term wound refers to an open wound that has re-epithelialized (page 6, lines 17-18).

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In view of Applicant's amendments, the 102(b) rejection of the last Office Action has been maintained for reasons of record and modified below as a result of Applicant's claim amendments in addition a modified 112-1st and new 112-2nd rejection in light of Applicant's amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 5-7 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the treatment of keloid and/or hypertrophic scar formation, does not reasonably provide enablement for the inhibition/prevention of of keloid and/or hypertrophic scar formation as recited in these claims.

The instant claims are drawn to a method for the inhibition/prevention of keloid and/or hypertrophic scar formation. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

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(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention:

The instant invention pertains to a method for the inhibition/prevention of keloid and/or hypertrophic scar formation.

The state of the prior art:

The skilled artisan would view that the inhibition/prevention of one or more symptoms of keloid and/or hypertrophic scar formation totally, absolutely, or permanently, is highly unlikely, since one cannot guarantee that the keloid and/or hypertrophic scar formation will always be prevented.

The relative skill of those in the art:

The relative skill of those in the art is very high.

The predictability or lack thereof in the art:

The skilled artisan would view that the treatment to inhibit/prevent of one or more symptoms of keloid and/or hypertrophic scar formation, absolutely, or permanently is highly unpredictable.

The amount of direction or guidance presented and the presence or absence of working examples:

In the instant case, no working examples are presented in the specification as filed showing how to prevent inhibit/prevent of one or more symptoms of keloid and/or hypertrophic scar formation totally, absolutely, or permanently. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

Genentech, Inc. v. Novo Nordisk, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test the combination in the instant claims whether inhibition/prevention of one or more symptoms of keloid and/or hypertrophic scar formation totally, absolutely, or permanently.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear from Applicant's statement of "in a course of therapy of wound or dermal injury," what stage of dermal or wound injury is being referred to. It is not clear if it is at the open wound stage or near the end at the scarring stage.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Cappelli-Schellpfeffer (WO 01/70210 A2).

Cappelli-Schellpfeffer teaches methods and compositions for improving the size and appearance of a healed wound, which may be a scar such as, a hypertrophic scar, a keloid, Dupuytren's contractures, acne scars, fibrotic scars, and reactive scars. Cappelli-Schellpfeffer teaches a topical method, which includes administering to an individual having a healed wound or scar a therapeutically effective amount of a

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cyclooxygenase inhibitor directly on the surface of the scar (page 13, lines 23-25). Note that acetylsalicylic acid is taught as a cyclooxygenase inhibitor (page 9, column 4-6).

Furthermore, Cappelli-Schellpfeffer teaches that by "improving" the size and appearance of a healed wound or a scar is meant to alleviate, either partially or completely, symptoms such as pain, tingling, itching, burning, discoloration; reducing the size of a scar; reducing surface irregularities; reducing the accumulation of fibrous tissue; and/or partially or completely eliminating the scar (page 11, line 23- line 27).

Additionally, Cappelli-Schellpfeffer teaches the composition is used to relieve or to prevent a condition of scar irritation, in particular in a case wherein scar irritation leads to symptoms including itching, and to a patient's self-inflicted mechanical action of scratching, which can result in further scar irritation, and possible contamination and invasion of the scar with native skin organisms (page 12, line 28-page 12, line 2).

Furthermore, Cappelli-Schellpfeffer teaches administering the cyclooxygenase inhibitor in amounts of 1 to 3000 μ g per square centimeter of treated tissue (page 24, lines 8-9), thus meeting the limitations of claims 3 and 5-7.

Conclusion

Claims 3 and 5-7 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617